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David R. Fischell

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ROSENBERG, KLEIN & LEE

3458 ELLICOTT CENTER DRIVE-SUITE 101

ELLICOTT CITY, MD 21043

EXAMINER

EVANISKO, GEORGE ROBERT

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



### **DETAILED ACTION**

The supplemental reply filed on 4/14/08 was not entered because supplemental replies are not entered as a matter of right except as provided in 37 CFR 1.111(a)(2)(ii). The supplemental reply is clearly not limited to placement of the application in condition for allowance (as seen by the new claims and art rejections below).

#### ***Election/Restrictions***

Claims 1-13 and 26-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 5/26/06.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25's limitations have been added to claim 14 and therefore should be canceled since it does not further limit the independent claim.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 14-17, 23, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stadler et al (6128526). Stadler describes the use of adjusting the start time of the sub-segment in columns 19 and 20 by using a formula for adjusting the time based on the R-R interval (e.g. col. 20). In addition, since he detects myocardial ischemia, he will inherently detect infarction and induced ischemia since they are both ischemias. Finally, Stadler discloses that the system can be implantable, implantable with programmer interaction, and an external/programmer device (e.g. figures 1A-1C) and that it provides alarms, allows physician viewing/display of stored ECG data, and real time viewing/display of ECG segments for myocardial ischemia (e.g. col. 8, lines 55-60, col. 10, line 5, col. 12, lines 50-63, cols. 13 and 14).

Stadler discloses the claimed invention except for using a look-up table for having predetermined start times corresponding to certain values of the R-R interval. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the cardiac event detection system and method as taught by Stadler, with using a look-up table for the start time corresponding to certain values of the R-R interval since it was known in the art

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that cardiac event detection systems and methods use a look-up table for associating values with other data, such as the start time corresponding to certain values of the R-R interval, to provide the predictable results of quickly associating the R-R interval with the proper start time without using microprocessor speed and calculation functions. In addition, in the alternative for the processing means for displaying the cardiac event, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the cardiac event detection system and method as taught by Stadler, the processing means for displaying the cardiac event, since it was known in the art that cardiac event detection systems and methods use a processing means for displaying the cardiac event to provide the predictable results of allowing the physician or patient to know what event is occurring, provide/display an alarm to the patient, and allow the patient to get help or allow the physician to send help or instructions to the patient.

Claims 18, 19, and 22 are rejected under 35 U.S.C. 103(a) as obvious over Stadler et al.

Stadler shows and describes the use of an average isoelectric point 1, the PQ segment (e.g. column 19 and figures 4, 5, etc), for use in analyzing the cardiac event and the use of T wave variation in column 18 for cardiac events.

In the alternative, Stadler discloses the claimed invention except for the averaging of sub-segments, such as the PQ segment, and the use of the T-wave peak as the sub-segment. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the cardiac event detection system and method as taught by Stadler, with the averaging of sub-segments, such as the PQ segment or ST segment, and the use of the T-wave peak as the sub-segment since it was known in the art that cardiac event detection systems and methods use

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the averaging of sub-segments, such as the PQ segment, to provide the predictable results of a more stable representation/estimation of the sub-segment and to use conventional cardiac sub-segments, such as the PQ and T wave peak, to provide the predictable results of accurately detecting cardiac events and conditions such as cardiac ischemia and arrhythmias.

Claims 20, 21, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stadler et al.

Stadler discloses the claimed invention except for excluding any beats where the R-R interval is shorter than 60 milliseconds, adjusting the start time in proportion to the square root of the R-R interval, and using a look-up table for the start time corresponding to certain values of the R-R interval. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the cardiac event detection system and method as taught by Stadler, with excluding any beats where the R-R interval is shorter than 60 milliseconds, adjusting the start time in proportion to the square root of the R-R interval, and using a look-up table for the start time corresponding to certain values of the R-R interval since it was known in the art that cardiac event detection systems and methods use: the excluding of any beats where the R-R interval is shorter than 60 milliseconds to provide the predictable results of preventing EMI or noisy beats from providing false indications of cardiac events, such as ischemia; adjusting the start time in proportion to the square root of the R-R interval to provide the predictable results of accurately adjusting the beginning of the sub-segment to reflect the increased/decreased length of the R-R interval using conventional calculations; and using a look-up table for the start time corresponding to certain values of the R-R interval to provide the

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predictable results of quickly associating the R-R interval with the proper start time without using microprocessor speed and calculation functions. In addition, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the cardiac event detection system and method as taught by Stadler with adjusting the start time in proportion to the square root of the R-R interval, because Applicant has not disclosed that adjusting the start time in proportion to the square root of the R-R interval provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with adjusting the start time based on the calculation as taught by Stadler, because it provides the predictable results of accurately moving the start time of the sub-segment based on the heart rate.

Therefore, it would have been an obvious matter of design choice to modify Stadler to obtain the invention as specified in the claim(s).

### ***Response to Arguments***

Applicant's arguments filed 3/28/08 have been fully considered but they are not persuasive. The argument that Stadler does not disclose a means for adjusting the start time by using a "look-up table having ...R-R intervals" is not persuasive. The examiner initially realized Stadler lacked this limitation (claim 25) in the first office action and provided a 103 rejection along with motivation for the modification of Stadler. The applicant has not argued that including the lookup table in Stadler would not be obvious and therefore the 103 rejection stands. In addition, the examiner has provided several references of many showing that including a table/look-up table in internal and external devices is well known and obvious.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The prior art patents 5323783, 5215098, 4519395, 6490479 are numerous examples of many showing the well known use of look-up tables to take the place of formulas or calculations in implantable and external devices to provide the predictable results of a fast approach to determine values and that reduces computer processing time and energy.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/  
Primary Examiner, Art Unit 3762

GRE  
5/30/08